REMARKS

Currently claims 1-21 are pending in the subject application. Claim 1 is amended and claims 18-21 are added. Support for the amendment to claim 1 may be found in the specification as filed. See, for example, paragraphs 0037, 0039, 0052, and 0057. Applicant believes that the amendment to claim 1 further clarifies the claim.

Support for claim 18 and 19 may be found in paragraphs 0039-0055. Support for claim 20 may be found in paragraphs 0053-0055

Suppport for claim 21 may be found in paragraphs 0057-0058.

Applicant reserves the right to pursue the subject matter of the claims prior to the amendment in a continuing application.

Interview Summary

Applicant's attorney wishes to express gratitude to the Examiner for the telephone interview of May 26th, 2006. The participants included applicant's representative, Sanjay Bagade and Examiner Matthews.

No exhibit was shown.

At this interview, the parties discussed the rejection of claim 1 in view of Unger (6,416,740). Applicant's attorney and the Examiner discussed the Unger reference and clarification as to the outstanding rejection. Applicant's attorney noted differences between claim 1 and Unger. However, no agreement was reached.

Applicant's attorney maintained the disagreement with the outstanding rejection but indicated a willingness to amend the claim for clarification.

Priority

The Office Action requested amendment of the first paragraph of the specification to show the correct status of the parent applications. In response, Applicant amended the first paragraph as indicated above.

Double Patenting - I

The Office Action rejected claims 1-7, 9, 10, 12, 14-17 on the ground of obvious-type double patenting over claims 1-7, 42 50-52, 57, 65-68 of US Patent No. 6,634,363. Applicant disagrees. However, to expedite allowance of the subject application, applicant reserves the right to submit a terminal disclaimer upon the indication that the claims are otherwise in condition for allowance.

Double Patenting - II

The Office Action rejected claims 1-6, 14-17 on the ground of obvious-type double patenting over claims 1-17 of US Patent No. 6,299,633. Applicant disagrees.

Claim 1 of the '633 patent recites a method of treating a bronchial tube in a lung having chronic obstructive pulmonary disease that comprises the step of advancing a treatment device to a treatment site in the bronchial tube, heating a wall of the bronchial tube to a temperature effective to form a region which increases the rigidity of the bronchial wall; and removing the treatment device from the treatment site.

In contrast, claim 1 of the subject application requires applying energy to a treatment site in lung tissue where the energy alters tissue at the treatment site reducing the ability of the tissue to produce at least one symptom of reversible obstructive pulmonary disease and controlling a temperature of tissue near the treatment site. Applicant notes that claim 2 requires reducing the temperature and claim 3 requires stabilizing the temperature. Applicant submits that subject claims are patentably distinct from the claims of the '633 application. However, to expedite allowance, applicant reserves the right to submit a terminal disclaimer upon the indication that the claims are otherwise in condition for allowance.

35 USC §102

The Office Action rejected claims 1-10, 12, 14-17 under 35 USC 102(e) as being anticipated by Unger US Pat. No. 6,416,740. Applicant disagrees with the rejection.

Unger teaches a targeted therapeutic delivery system comprising a gas or gaseous precursor filled microsphere wherein said gas or gaseous precursor filled microsphere comprises an oil, a surfactant, and a therapeutic compound. Unger also teaches methods of preparing the targeted therapeutic delivery system and a method comprising processing a solution comprising an oil and a surfactant in the presence of a gaseous precursor, at a temperature below the gel to liquid crystalline phase transition temperature of the surfactant to form gas or gaseous precursor filled microsphere, and adding to said microspheres a therapeutic compound resulting in a targeted therapeutic delivery system, wherein said processing is selected from the group consisting of controlled agitation, controlled drying, and a combination thereof. (See e.g., Unger col. 2, lines 30-45).

Unger further teaches in col. 65, lines 22-39 use of ultrasound to promote rupture of vesicles once the vesicles reach the intended target, including tissue and/or receptor destinations, thus releasing a bioactive agent, such as a steroid prodrug. Applicant notes that Unger specifically teaches that a vesicle is a carrier of a various materials and may include "liposomes, lipospheres, particles, nanoparticles, micelles, bubbles, microbubbles, microspheres, lipid-coated bubbles, polymer-coated bubbles and/or protein-coated bubbles, microbubbles and/or microspheres, nanospheres, microballoons, microcapsules, aerogels, clathrate bound vesicles, hexagonal H II phase structures, and the like". (See Unger col – e.g. col. 5, starting at line 33.)

Applicant believes that Unger teaches the use of energy to aid in the delivery of therapeutics rather than applying energy to a treatment site in lung tissue and controlling a temperature of tissue near the treatment site.

The Office Action refers to Unger col. 35, lines 20-34. Applicant believes this section does not teach or suggest the requirements of claim 1.

The Office Action refers to Unger col. 69 line 42 to col. 70 line 55 and col. 77, line 12 to col. 78, line 37. Again, applicant believes that this section teaches the use of ultrasound tobreak apart the delivery vehicles discussed therein and release the drug at the treatment

region. Furthermore, in this section, Unger teaches delivery of liquids to areas of elevated temperatures (typically associated with disease, inflammation, infection, etc.) and incorporating materials which are liquid at normal physiological temperatures (i.e. the temperature of a particular mammal under normal circumstances) and which undergo a phase transition to form a gas at the elevated temperature to allow steroid prodrugs to be effectively delivered to the affected tissue and advantageously released at that site. Applicant submits that this teaching seems to rely on areas of elevated temperatures rather than controlling the temperature of tissue near the treatment site.

Applicant requests clarification as to where Unger teaches or suggests, at the very least, applying energy to a treatment site in lung tissue where the energy alters tissue at the treatment site reducing the ability of the tissue to produce at least one symptom of reversible obstructive pulmonary disease and controlling a temperature of tissue near the treatment site. In the absence of such clarification, applicant requests withdrawal of this rejection as to claim 1 and all claims ultimately dependent therefrom.

35 USC §103 –I

The Office Action rejected claim 11 under 35 USC 103(a) as being unpatentable over Unger US Pat. No. 6,416,740 in view of Lorentzen US Pat. No. 5,951,546. Applicant disagrees that the Office Action establishes a proper prima facie case of obviousness.

In view of the above, applicant notes that Unger fails to teach or suggest the requirements of claim 1. Lorentzen does nothing to remedy the defects of Unger with respect to, at the very least, claim 1. On this basis alone, applicant submits a proper prima facie rejection is not established.

Furthermore, Unger is directed to targeted therapeutic delivery systems comprising a gas or gaseous precursor filled microsphere wherein said gas or gaseous precursor filled microsphere comprises an oil, a surfactant, and a therapeutic compound. Lorentzen teaches tissue ablation useful for forming lesions in tissue, whereby tumors, birth marks, or the like may be removed. Given that Lorentzen is directed to tissue removal, and Unger is directed to therapeutic delivery systems, applicant believes that one would not look to Lorentzen to modify the delivery system of Unger.

In view of the above, applicant requests withdrawal of this rejection.

35 USC §103 –II

The Office Action rejected claim 13 under 35 USC 103(a) as being unpatentable over Unger US Pat. No. 6,416,740 as applied to claims 1, 3-10, 12, 14-17 and further in view of Stern US Pat. No. 5,741,248. Applicant disagrees that the Office Action establishes a proper prima facie case of obviousness.

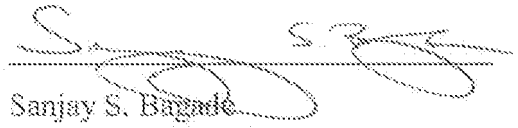
Again, applicant notes that Unger fails to teach or suggest the requirements of claim 1. Stern does nothing to remedy the defects of Unger with respect to, at the very least, claim 1. On this basis alone, applicant submits a proper prima facie rejection is not established.

Stern teaches a method for cryogenic treatment of a lesion which includes the steps of delivering a fluorochemical liquid to the lesion, placing at least one cryoprobe into the lesion, and circulating cryogenic fluid through the cryoprobe, the cryogenic fluid causing an ice ball to form in a vicinity around the cryoprobe, wherein the ice ball obliterates at least a portion of the lesion. . Given that Stern is directed to ablation using cyrogenic fluid/cryorobe, and Unger is directed to therapeutic delivery systems, applicant believes that one would not look to Stern to modify the delivery system of Unger.

SUMMARY

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

Respectfully submitted,



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